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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,224	12/21/2001	Timothy E. Benson	00403.CN1	4497

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,224

Applicant(s)

BENSON ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, page 12, line 2; page 40, line 27; page 42, line 24; and elsewhere. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks SEQ ID Nos cited along with each sequence in the specification or Figures. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy, or CD-ROM for the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached titled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is mailed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4 and 37-40, drawn to a glycosylated molecule or molecular complex comprising a portion of a human beta secretase binding pocket or a molecule structurally homologous to a human binding secretase molecule or molecular complex, classified in class 702, subclass 27 and class 530, subclasses 300 and 350. If this Group is elected, then TWO of the below summarized specie elections are also required.
- II. Claims 5-15 and 41-49, drawn to a scalable three-dimensional configuration of points and a machine-readable data storage medium, classified in class 702, subclass 27 and class 211, subclass 41.12. If this Group is elected, then TWO of the below summarized specie elections are also required.
- III. Claims 16 and 50, drawn to a method for obtaining structural information about a molecule or molecular complex of unknown structure, classified in class 702, subclass 27. If this Group is elected, then ONE of the below summarized specie elections is also required.
- IV. Claims 17 and 51, drawn to a method for homology modeling a human beta secretase homolog, classified in class 703, subclass 2. If this Group is elected, then ONE of the below summarized specie elections is also required.
- V. Claims 18-30 and 52-53, drawn to a computer-assisted method for identifying an inhibitor of human beta secretase activity, classified in class 702, subclass 19. If this Group is elected, then ONE of the below summarized specie elections is also required.

- VI. Claims 31-33, drawn to a method for making an inhibitor of human beta secretase activity, classified in class 702, subclass 27 and 435, subclass 7.1.
- VII. Claims 34-36, drawn to an inhibitor of human beta secretase activity as well as a composition containing the same, classified in class 530, subclasses 300 and 350 as well as class 514, subclass 1. If this Group is elected, then ONE of the below summarized specie elections is also required.
- VIII. Claims 54-71, drawn to a method for crystallizing a human beta secretase molecule or molecular complex, classified in class 530, subclass 344, and class 436, subclass 4. If this Group is elected, then THREE of the below summarized specie elections are also required.
- IX. Claims 72-76, drawn to a crystal of beta secretase, classified in class 702, subclass 27, and class 530, subclass 350.
- X. Claims 77-78, drawn to a method of producing human beta secretase, classified in class 435, subclass 69.1. If this Group is elected, then ONE of the below summarized specie election is also required.

Specie Election Requirement for Groups I-V, VII-VIII, and X:

This application contains claims directed to the following patentably distinct species of the claimed invention:

First Specie Election Requirement for Groups I-II and

Only Specie Election Requirement for Groups III-V and VII:

Specie A: using structural coordinates listed in Table 1

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Specie B: using structural coordinates listed in Table 3

Second Specie Election Requirement for Groups I-II:

Specie C: binding pocket which comprises amino acids listed in Table 5

Specie D: binding pocket which comprises amino acids listed in Table 6

Specie E: binding pocket which comprises amino acids listed in Table 7

First Specie Election Requirement for Group VIII:

Specie F: a salt which is sodium chloride

Specie G: a salt which is ammonium sulfate

Specie H: a salt which is magnesium sulfate

Specie I: a salt which is lithium sulfate

Specie J: a salt which is a combination of salts

Second Specie Election Requirement for Group VIII:

Specie K: a glycol which is PEG

Specie L: a glycol which is PEG-MME

Specie M: a glycol which is PEG-DME

Specie N: a glycol which is polyoxyalkylenepolyamines

Specie O: a glycol which is a combination of glycols

Third Specie Election Requirement for Group VIII:

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Specie P: a human beta secretase which is isolated from mammalian cells

Specie Q: a human beta secretase which is isolated from insect cells

Only Specie Election Requirement for Group X:

Specie R: a cell line which is mammalian

Specie S: a cell line which is from insects

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for each applicable specie election requirement for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness of structural coordinates listed in Table 1 versus Table 3 (Groups I-V and VII) is because these are structurally distinct entities containing functionally distinct properties. The distinctness of binding pocket which comprises amino acids listed in Table 5 versus Table 6 versus Table 7 (Groups I-II) is because these listings contain different sets of amino acids that make them structurally and functionally unique. The distinctness or independence of a sodium chloride versus ammonium sulfate versus magnesium sulfate versus lithium sulfate versus combination of salts (First specie election requirement for Group VIII) and PEG versus PEG-MME versus PEG-DME versus polyoxyalkylenepolyamines versus a combination of glycols (Second Specie Election Requirement for Group VIII) is because these species are separate chemical and entity types of the invention which are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough

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processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. The distinctness of mammalian cells versus insect cells (Groups VIII and X) is because these entities are from different phyla containing distinctly different characteristics. Thus, the above-mentioned species are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groupings [I-VI, VIII, and X], VII, and IX are independent inventions because they are directed to different chemical and entity types regarding the critical limitations therein. For Groups I-VI, VIII, and X; the critical feature is molecule or molecular complex comprising a human beta secretase. For Group VII, the critical feature is an inhibitor. For Group IX, the critical feature is a crystal. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the three Groupings [I-VI, VIII, and X], VII, and IX are independent and/or distinct invention types for restriction purposes.

Inventions in Groups I-VI, VIII, and X are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the molecule of Group I may be utilized in distinct usages as needed in Group II for a scalable three-dimensional configuration of points, in a method for obtaining structural information about a molecule or a molecular complex of unknown structure as in Group III, in a method for homology modeling a human beta secretase homolog as in Group IV, in a computer-assisted method for identifying an inhibitor of human beta secretase activity as in Group V, in a method for making an inhibitor of human beta

secretase activity as in Group VI, in a method for crystallizing a human beta secretase molecule or molecular complex as in Group VIII, in a method of producing human beta secretase as in Group X, or alternatively, in various x-ray crystallography studies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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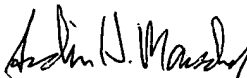
1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 5, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER